PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant:	Charmaine K. Harris; Joseph J. Klein	Confirmation No.	3255
Serial No.:	10/773,121	Filed:	February 5, 2004
Examiner:	Alyssa M. Alter	Group Art Unit:	3762
Docket No.:	1023-270US02	Customer No.:	28863
Title:	PERCUTANEOUS FLAT LEAD INTRODUCER		

CERTIFICATE UNDER 37 CFR 1.8 I hereby certify that this correspondence is being transmitted via the United States Patent and Trademark Office electronic filing system on October 12, 2010.

By: /Shirley A. Betlach/
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REQUEST FOR REHEARING UNDER 37 C.F.R. § 41.52

Commissioner for Patents
Alexandria, VA 22313

Dear Sir:

This is a Request for a Rehearing in accordance with 37 C.F.R. § 41.52 in response to the Board decision dated August 11, 2010. In accordance with 35 U.S.C § 21, the deadline for submission of this Request is Tuesday, October 12th, 2010, Monday, October 11th, 2010 being a Federal holiday.

Please charge any fees that may be required or credit any overpayment to Deposit Account No. 50-1778.

REMARKS

The Board decision dated August 11, 2010 correctly reversed the Examiner's rejections of claims 1-5, 7-37 and 44-50. However, the Board decision affirmed the rejection of Group 4 (claims 38-40, 42 and 43) under 35 U.S.C. § 103(a) as being unpatentable over US 2002/0147485 by Mamo et al. (Mamo) in view of US 6,146,371 to DeWindt et al. (DeWindt). Applicant request reconsideration of the rejection of Group 4 as there is no apparent reason one of ordinary skill in the art at the time of Appellant's invention would have found the subject matter of Appellant's claims 38-40, 42 and 43 to have been obvious.

Independent claim 38 recites a dilator for widening a path for a stimulation lead to travel through an epidural region proximate a spine of a patient, the dilator having a proximal end and a distal end, wherein the dilator defines a dilator lumen sized to advance over a guidewire, the dilator having a substantially conical distal tip, wherein at least a portion of the conical distal tip has a substantially oblong cross-section, wherein the dilator lumen has a substantially oblong cross-section.[1] Claims 39, 40, 42 and 43 are dependent on claim 38, and are patentable for at least the reasons claim 38 is patentable.

In support of the decision to affirm the rejection of Group 4, the Board concluded that Mamo discloses a dilator lacking an oblong cross-section and that DeWindt discloses an oval-shaped cannula.[2] In addition, the Board asserted that:[3]

> One of ordinary skill in the art would recognize that minimizing invasiveness to the patient by using the cross sectional shape disclosed by DeWindt would be a predictable advantageous feature of a variety of surgical instruments, including Mamo's dilator. Thus, we find Appellants' argument that the Examiner's proposed combination would have failed to render obvious a dilator tip having a "substantially oblong cross-section" is unpersuasive.

The Board's reasoning represents a new argument. In contrast to the Board's argument, the Examiner asserted that a person of ordinary skill in the art would have sought to modify the dilator of Mamo with the oblong or oval shape of DeWindt to utilize available space more

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[1] *See* Appellant's specification as filed, page 7, paragraphs [0034]-[0035] and FIG. 3.
[2] Decision on Appeal, dated August 11, 2010, page 4.
[3] *Id.*

efficiently.[4] Applicant hereby addresses the new argument provided by the Board, i.e., that the cross sectional shape disclosed by DeWindt would "minimize invasiveness" in the dilator of Mamo.

Appellant respectfully disagrees with the Board's reasoning. The Board's decision failed to include any explanation as to how modifying the dilator disclosed by Mamo to include a dilator tip having a "substantially oblong cross-section" would minimize invasiveness or otherwise be advantageous. However, the oval shape disclosed by DeWindt would not provide any apparent advantage in the dilator disclosed by Mamo. In fact, in direct contrast to the Board's assertion, modification of the dilator disclosed by Mamo to include a dilator tip having a "substantially oblong cross-section" would likely increase the invasiveness of a procedure using the dilator disclosed by Mamo.

Mamo discloses that the dilator disclosed by Mamo is part of a surgical implantation kit used to implant a stimulation lead in a patient's sacrum.[5] Mamo further discloses that the diameter of the dilator is sufficient for inserting a stimulation lead.[6] The only stimulation lead disclosed by Mamo is stimulation lead 30, and stimulation lead 30 includes a round cross-section. For example, lead 30 is depicted in Mamo, FIGS. 2, 5e – 5k, 6j – 6l, 6o, 7e – 7g, 9f and 9g. In each instance, lead 30 is represented as having a tubular lead body with ring electrodes. A modified dilator would still need to create a path sufficient for inserting stimulation lead 30. A dilator including an oblong-cross section would be have to be larger than a dilator including a circular cross-section in order to create a path sufficient for inserting stimulation lead 30. For this reason, modifying the dilator disclosed by Mamo to include an oblong-cross section would unnecessarily increase the size of the dilator and thereby increase the invasiveness of a procedure using the dilator to insert stimulation lead 30 within a patient. In this manner, one of ordinary skill in the art would likely have avoided modification of the dilator disclosed by Mamo to include an oblong-cross section. At the very least, the suggested modification would appear to have the opposite effect of "minimizing invasiveness" as offered in support of the rejection.

The Board relied on DeWindt as disclosing an oval shape that would provide "a predictable advantageous feature of a variety of surgical instruments, including Mamo's dilator." However, as discussed above, the oval shape disclosed by DeWindt would not provide any apparent advantage in the dilator disclosed by Mamo, and may indeed be disadvantageous by

[4] Final Office Action mailed March 6, 2007, page 5.
[5] Mamo, abstract.

unnecessarily expanding the dilator profile. For this reason, the Board's decision lacks an apparent reason why one of ordinary skill in the art would have found it obvious to modify Mamo's dilator to include a tip having a "substantially oblong cross-section" as required to support the rejection of independent claim 38 and dependent claims 39, 40, 42 and 43.

For these reasons, the decision of the Board did not establish a *prima facie* case of obviousness for claim 38 as required to support a rejection under 35 U.S.C. §103(a). Appellant respectfully requests reversal of the rejection of claim 38 and dependent claims 39, 40, 42 and 43.

CONCLUSION OF ARGUMENT

The Board and the Examiner have failed to provide a *prima facie* case of obviousness with respect to claim 38. For this reason, Appellant respectfully requests reversal of the Board decision affirming the rejection of independent claim 38 and dependent claims 39, 40, 42 and 43.

All claims are in condition for allowance. Appellant respectfully requests reversal of the Examiner rejections and allowance of claims 38-40, 42 and 43.

Respectfully submitted,

Date: October 12, 2010

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[6] *Id.*